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(54) Catheter

(57) A catheter, which is suitable especially for use as a gastrostomy tube, is provided at each end with transversely-extending retaining portions (11, 13) which are intended to engage, respectively, an external and an internal surface of the body to retain the tube in position. The catheter includes a valve (15) which permits the insertion of one end of a length of tubing (25, Fig. 3) to enable a fluid to be passed into the body via openings at the internal end of the tube. The valve (15), which is self-sealing and closes when the tubing is removed, can be located within the mouth of the catheter tube or in a separately-formed portion (43) secured to the tube. The retaining portions (13) at the internal end of the catheter tube are deflectable to facilitate insertion of the tube in the body.

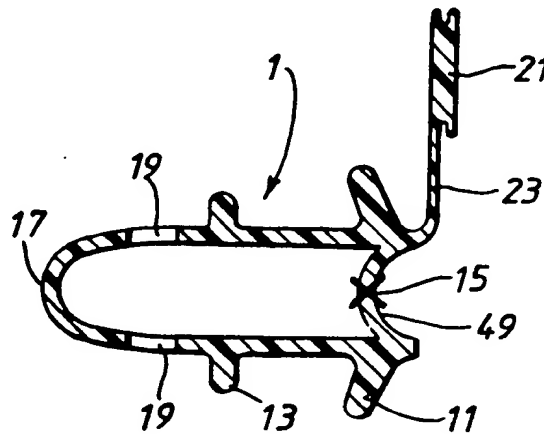
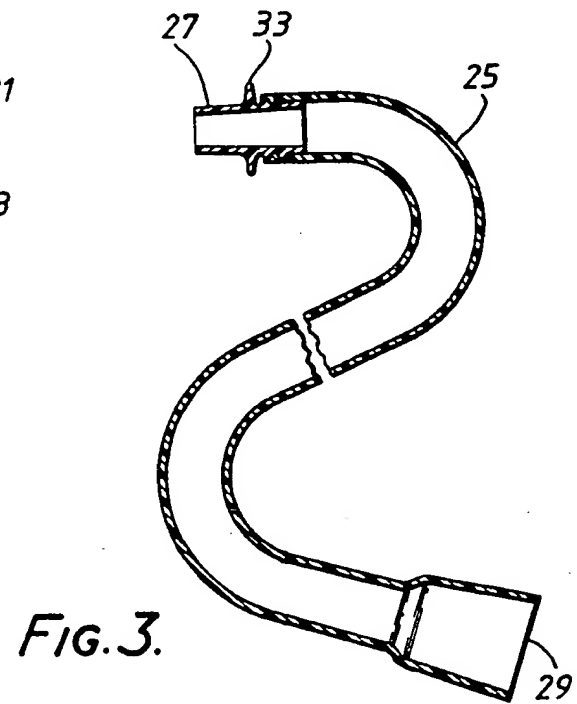
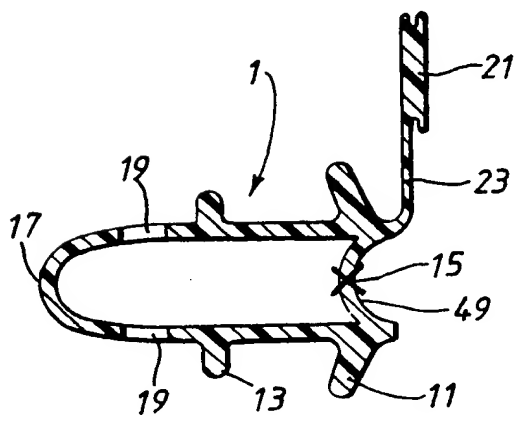
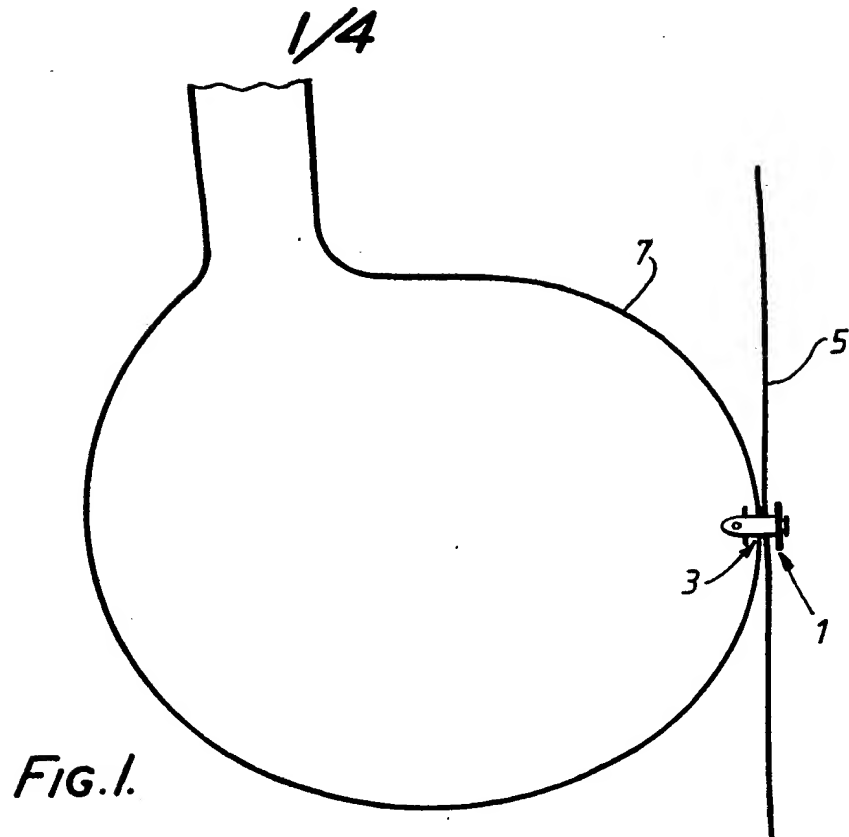


FIG. 2.

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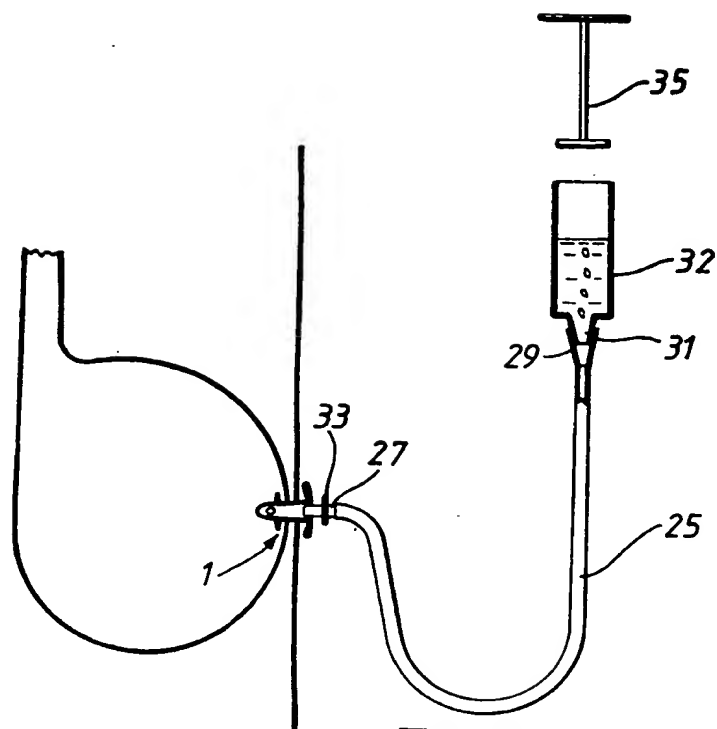


FIG. 4.

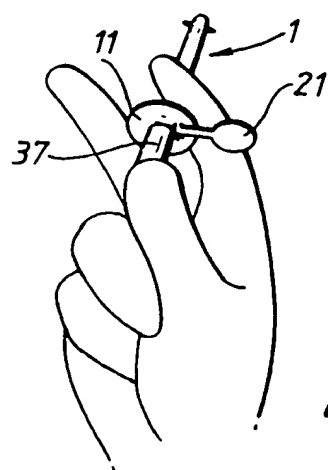
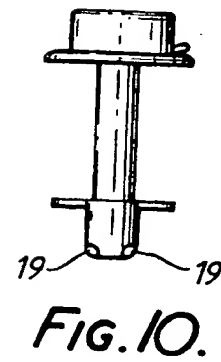
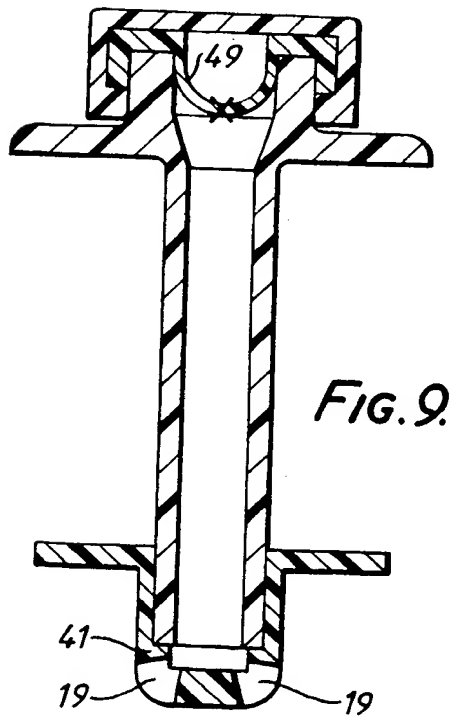
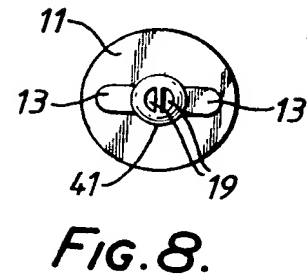
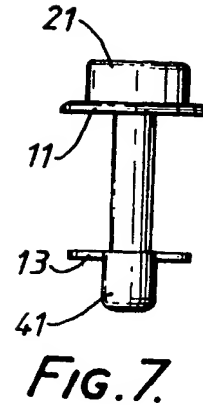
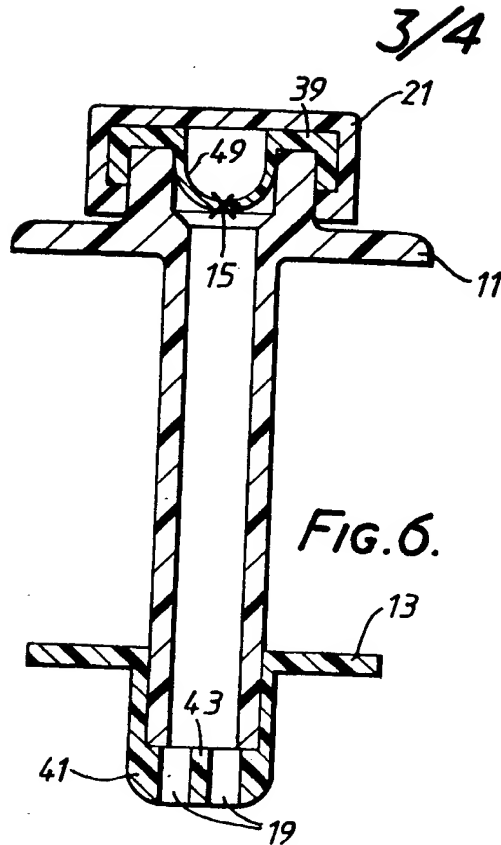
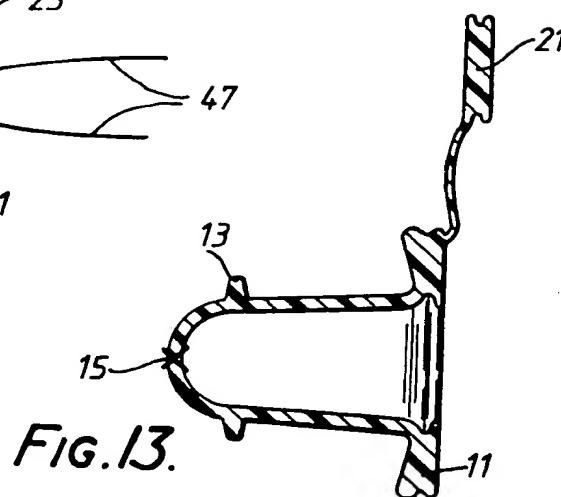
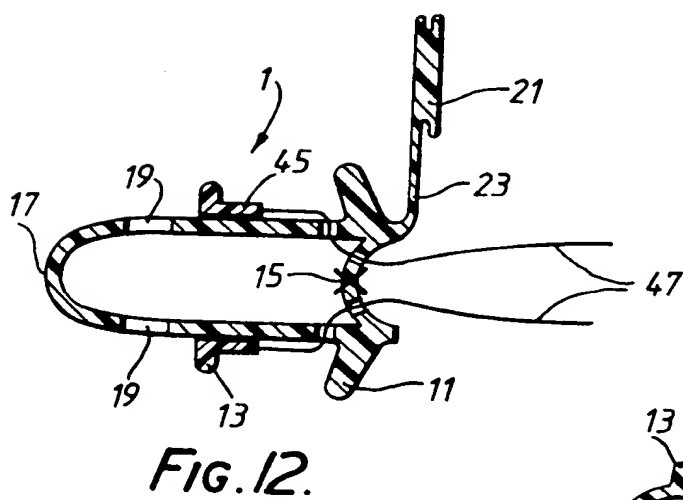
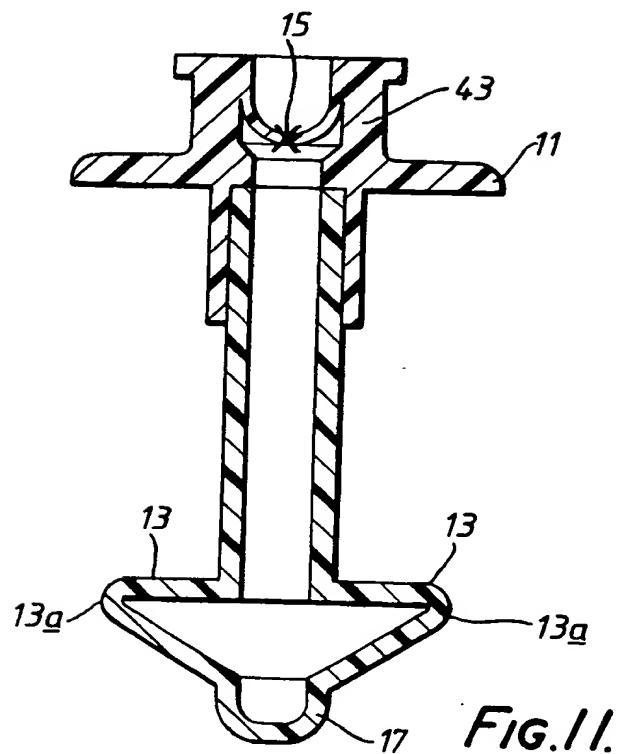


FIG. 5.



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SPECIFICATION

Catheter

- 5 This invention relates to catheters and, more especially, to a catheter suitable for use as a gastrostomy tube.

Gastrostomy is a medical procedure, the function of which is to provide a means
10 whereby fluid feed can be passed directly into the stomach through the abdomen wall. This procedure is employed in cases where oral feeding is either not physically possible or where, for medical reasons, it is to be
15 avoided, eg, in the case of Dysautonomia. Gastrostomy involves the insertion of a tube, through a surgically provided opening (or stoma) in the wall of the abdomen, into the stomach. In use, the tube allows not only the
20 passage of fluid feed directly through the abdomen wall into the stomach but also the release of gas from the stomach.

A catheter in current use as a gastrostomy tube consists of a long rubber tube, one open
25 end of which is configured to be retained within the stomach. The remainder of the tube, which is of some length, hangs outside the body and the external open end of the tube is plugged with a plastic spigot. This
30 functions adequately and does provide a solution to feeding problems such as those experienced by dysautonomic children, but the design of the catheter presents a number of practical problems, particularly in children. For
35 example, the spigot is bulky and is difficult to replace after feeds because it tends to be ejected by the wet tubing. Also, because the external part of the tube is so long, a child's normal activity causes it excessive movement
40 and pulling and so, to prevent the tube being accidentally pulled out and to prevent soreness of the stoma, the tube must be coiled around the spigot and taped securely to the body. This bulk of sticky tape and coiled tubing
45 stops air from circulating around the area of the stoma and a gauze pad must therefore be taped around the stoma to keep it dry and healthy. This elaborate system of sticky tape and coiled tubing considerably delays a child's
50 ability to manage his gastrostomy independently. Moreover, the overall appearance of the gastrostomy is unsightly and the tube is conspicuous even under clothes, and this may pose both practical and psychological problems.
55

It is an object of the present invention to enable these difficulties to be reduced.

The present invention provides a catheter which is so shaped that, in use, the external
60 end thereof is retained adjacent an external surface of the body and which includes a valve operable by the insertion of a fluid flow member to permit the flow of fluid through said member into or out of the body.

65 The valve is arranged to close in response

to the removal of the fluid flow member, to prevent the flow of fluid through the catheter into or out of the body. The valve may be located at the said external end.

- 70 The catheter may be used in combination with a fluid flow member shaped for insertion in the catheter to open the valve and carry fluid into or out of the body.

When a catheter in accordance with the invention is used as a gastrostomy tube it can be used to carry fluid both into and out of the body in that it can be used both to release
75 gases from the stomach and to carry fluid feed into the stomach.

80 The catheter tube may be provided with shaped portions at each end to retain the tube in position in the body. Advantageously, the length of the catheter tube between the shaped portions can be altered. The
85 transversely-extending portions for engagement with the internal body surface may be movable or deformable to permit insertion of the catheter in the body.

By way of example, embodiments of the invention will now be described with reference to the accompanying drawings, in which:

Fig. 1 illustrates, diagrammatically, the use of a catheter in accordance with the invention as a gastrostomy tube;

95 Fig. 2 shows a longitudinal section through the gastrostomy tube of Fig. 1;

Fig. 3 shows, in longitudinal section, a component for use with the tube of Fig. 2;

Fig. 4 illustrates a feeding operation;

100 Fig. 5 illustrates insertion of the gastrostomy tube;

Fig. 6 is a view similar to Fig. 2 of another form of gastrostomy tube;

105 Figs. 7 and 8 are, respectively, a side view and a view from one end on a reduced scale of the tube of Fig. 6;

Figs. 9 and 10 are views, similar to Figs. 6 and 7, of a modified tube, and

110 Figs. 11 to 13 are views similar to Fig. 2 of other forms of gastrostomy tube.

Fig. 1 shows, diagrammatically a gastrostomy tube 1 which has been inserted through a surgically-provided stoma 3 in the wall of the abdomen 5 into the stomach 7. The stomach wall and the internal abdomen wall are sutured together in the region of the stoma and the tube 1, which is formed of a material that may be safely retained within the stomach for prolonged periods of time, allows
115 the through-passage to the stomach of liquid feed, as described below.

The tube 1 (shown in greater detail in Fig. 2) is a generally cylindrical capillary tube of such a length that, with one end located inside the stomach, the other end lies adjacent the external surface of the abdomen. The external end of the tube is provided with a flange 11 to prevent it being drawn in through the stoma and into the stomach and projects
120 approximately 1/2cm from the outer surface

of the body. The internal end of the tube is provided with lugs 13 to ensure that this end is retained within the stomach wall until such time as the tube is removed. The internal end

5 tip 17 of the tube is closed but openings 19 are provided in the tube wall adjacent the tip. A self-sealing closure, or valve, 15 is provided within the external end of the tube: this valve 15 is opened during a feeding operation as described below but otherwise remains tightly closed, resisting pressure of liquid or gas which may build up within the stomach. A cap 21 is provided to fit over the external end of the tube for the purpose of sealing and protecting the external mouth of the tube from the accidental entry of any foreign body, when not in use: the cap 21, which is shown removed in Fig. 2 is permanently attached to the tube by a link 23.

20 During a feeding operation, the tubing 25 shown in Fig. 3 is used in combination with the gastrostomy tube of Fig. 2. The tubing 25, which is approximately 18 inches long and has a diameter compatible with that of the tube 1, has a nozzle 27 securely fitted (or integrally formed) in one end. This nozzle 27 is suitably shaped for insertion into the tube to intercept and open the valve 15 therein. The other open end 29 of the tubing 25 is shaped to be a friction fit on, or to be attachable in some other suitable way, to the funnel of a syringe, or other suitable vessel, containing a fluid feed.

When the nozzle 27 is fitted into the tube 35 1, the overall length of the assembly is comparable to that of conventional catheters now in use as gastrostomy tubes.

The sequence of steps in a feeding operation, (which is illustrated in Fig. 4) is as follows. First the cap 21 is removed from the external end of the tube 1 with the fingers of one hand, whilst the flange 11 is held steady by the fingers of the other hand. During this step, the valve 15 remains tightly sealed against internal pressure from the stomach contents. The open end 29 of tubing 25 is fixed securely on to the funnel 31 of a receptacle (in this instance, a syringe 32) containing fluid feed and the nozzle 27 at the other end of the tubing is then inserted into the uncapped end of the gastrostomy tube 1 until it intercepts valve 15. The nozzle 27 is then pushed further into the tube 1, opening and entering the valve 15 until a ridge 33 circumscribing the nozzle meets the external end of the tube 1. The introduction of the nozzle 27 into the valve 15 provides a through-opening to the stomach and, once in position, the nozzle 27 is held securely in place by the close fit of the valve 15.

While the nozzle 27 is being inserted using one hand, the external end of the gastrostomy tube 1 is gripped between the fingers of the other hand to prevent pressure being transmitted to the stoma 3. The syringe 32

containing the feed may be supported by one arm or in any convenient manner. Once the nozzle 27 is in position, the plunger 35 of the syringe 32 is removed to allow gas to escape from the stomach by passing through the connected parts 1, 25 and bubbling up through the feed in the syringe into the air as shown in Fig. 4. The syringe is held, at a higher level than that of the stoma, allowing feed to pass under gravity into the stomach. The plunger 35 may be used to assist the flow of feed, if necessary. When the feed is finished, the nozzle 27 is removed by pulling gently with one hand, whilst the fingers of the other hand hold the external end of tube 1 steady against the body. As the nozzle 27 is removed, the valve 15 re-seals. Cap 21 is replaced and tubing 25 can be cleaned and put away till next required. If desired, the external end of tube 1 can then be completely concealed by the application of a small air-strip plaster.

Occasionally, the gastrostomy tube 1 may need to be replaced. This is simply done by gripping the external end and pulling steadily until the tube is withdrawn through the stoma, this procedure being facilitated by both the design of the internal end of the tube and the material used. Accidental removal, on the other hand, is unlikely to occur because the external end of the tube is almost flush to the skin of the abdomen and not likely to be caught by clothes, etc.

To insert a new tube, a rigid former 37, longer than the tube, is first inserted through the valve 15 and the tube is then stretched down over the former 37 by placing the fingers of one hand immediately behind the flange 11 of the tube and applying constant pressure to the exposed end of the former 37 with the thumb, as shown in Fig. 5. The diameter of the tube 1 is reduced as the tube is stretched and the action of the former on the closed tip 17 of the tube causes the latter to become more pointed. The tube is then easily inserted through the stoma into the required position in the stomach. The fingers are then removed from behind the flange 11 so that the tube 1 is no longer stretched and, by holding the external end of the tube steady against the skin of the abdomen, the rigid former 37 can be withdrawn while the tube is retained in position. The lugs 13 are so shaped that during insertion of the tube 1 as just described, they deflect backwards as necessary to enable the tube to be inserted through the stoma. When the tube is in position, however, and no longer stretched, the lugs lie at 90° to the tube and resist removal of the latter.

Figs. 6 to 8 illustrate another form of catheter, also for use as a gastrostomy tube, which is not moulded in one piece and offers the advantages of being comparatively simple to produce and of allowing the length of the tube to be adjusted to meet requirements.

The tube shown in Figs. 6 to 8 which, as before, has a removable cap is of the same general form as that shown in Fig. 2, with a flange 11 and a self-sealing valve 15 at the external end and lugs 13 and openings 19 at the internal end. As before, the flange 11 is formed in one piece with the tube but the valve 15 is formed in a separate member 39 secured to the external end of the tube, and the lugs 13 and openings 19 are formed in another separate member 41 secured to the internal end of the tube. In this case the openings 19 are not formed in the side of the tube but in the tip and extend parallel to the bore of the tube, with a web 43 between them on which the former 37 (Fig. 5) can act when the tube is being inserted. Advantageously, the former is provided with a groove in its tip in which the web 43 can locate.

The components 39, 41 are secured to the ends of the tube 1 by a suitable bonding agent. The tube 1 may be formed from a high tear strength silicon material, for example a silastic medical grade elastomer in which case the bonding agent may be a silastic adhesive. Before the member 41 is secured, the tube 1 is cut to the required length.

A modification of the tube shown in Figs. 6 to 8 is shown in Figs. 9 and 10. In this modification, the internal shaping of the member 41 secured to the internal end of the tube is changed to allow the openings 19 to be moved towards the sides of the tube and to be enlarged. This reduces any possibility that the openings 19 will become blocked. In addition, the internal shaping of the bore of the tube at the external end is changed to correspond more closely to the shape of the nozzle 27 used during feeding so that a greater portion of the nozzle can enter the bore to provide a more secure attachment in use.

Yet another form of tube, which also permits the length of the tube to be adjusted, is shown in Fig. 11. In this case, the lugs 13 and the end tip 17 (against which the former 37 acts) are formed in one piece with the tube but the flange 11 and valve 15 at the other end of the tube are formed in a separate member 43. The length of the tube is adjusted at this end and the member 43 is then secured to the tube by a suitable bonding agent. The lugs 13 of this embodiment are of a different form from those of the previously-described embodiments in that each lug comprises a strip of material attached at one end to the end of the tube. The strip extends at 90° from the tube and is then bent back on itself at 13a and is joined, at its other end, to the other strips by the tip portion 17. Pressure applied against the tip 17 by the former 37 as illustrated in Fig. 5 straightens out the strip-like lugs 13 (moving the tip 17 away from the end of the tube) and facilitates insertion of the tube through the stoma.

An alternative arrangement for adjusting the

effective length of the tube without cutting the tube is illustrated in Fig. 12. The lugs 13 are formed on a separate member 45 which is movable along the external surface of the tube and provided with cords 47 which extend through the external end of the tube and permit the position of the member 45 along the length of the tube to be adjusted when the latter has been inserted. In yet another alternative arrangement (not illustrated) the lugs 13 are fixed and the tube is formed with corrugations, in the manner of bellows, enabling the length of the tube to adjust as required without the need to cut the tube.

In each of the embodiments described above, the valve 15 is located at the external end of the tube 1. This is not essential, however, and the valve could be located at any point along the bore of the tube. Fig. 13, for example, shows a tube in which the valve 15 forms the internal tip of the tube.

The valve 15 may have any suitable form, provided that it is self-sealing and can be opened by the insertion of the nozzle 27 (Fig. 3). In the embodiments described above, the valve is formed by a simple slit in the base of a curved wall 49, into which the nozzle 27 can be inserted but the sides of which close together when the nozzle is removed.

The single flange 11 of the above-described embodiments can be replaced by two or more lugs and the number of lugs 13 can be varied as required. The end cap 21 can be replaced, if wished, by a plug.

The self-sealing gastrostomy tubes described above minimize many of the major problems associated with catheters in current use as gastrostomy tubes. They require no spigot, so the associated problems of ejection are avoided. The shape and size of the external end of each of the tubes allow circulation of air around the stoma which remains naturally dry so that a gauze pad is not required, although a small gauze disc can, if required, be inserted between the flange 11 and the skin of the abdomen. To assist ventilation of the stoma area further, the flange 11 can be provided with perforations or vents. After a feeding operation, the long tubing 25 is removed and no fiddly coiling or sticky tapes are necessary so that only limited dexterity is required, a point of particular importance to children in promoting a child's independent management of his gastrostomy. As the small external portion of the tube is almost flush to the body, it is completely inconspicuous when covered by a small plaster so that any social or psychological problems related to the appearance of the gastrostomy are minimised.

Finally, although the self-sealing catheters described above are specifically intended for use as gastrostomy tubes, it is envisaged that catheters constructed as described will have wide application in other areas either for fluid entry or for drainage of body fluid, for

example from the bladder or chest.

Typically, a child's gastrostomy tube such as that shown in Figs. 6 to 8 is manufactured to have an overall length in the region 3.5 cm (to allow adjustment) and an external diameter of 0.5 cm. The flange 11 has an external diameter of 2.0 cm.

CLAIMS

1. A catheter which is so shaped that, in use, the external end thereof is retained adjacent an external surface of the body and which includes a valve operable by the insertion of a fluid flow member to permit the flow of fluid through said member into or out of the body.

2. A catheter as claimed in claim 1, in which the valve is arranged to close in response to the removal of the fluid flow member, to prevent the flow of fluid through the catheter into or out of the body.

3. A catheter as claimed in claim 1 or claim 2, in which the valve is located at the said external end.

4. A catheter as claimed in claim 3, having at least one opening at the other end for communication with the interior of the body.

5. A catheter as claimed in any one of the preceding claims, in which the valve is located in a transverse wall in the bore of the catheter tube.

6. A catheter as claimed in claim 5, in which the valve comprises a slit in the transverse wall, arranged to permit the insertion of the fluid flow member and to close in response to removal of the member.

7. A catheter as claimed in any one of the preceding claims, in combination with a fluid flow member shaped for insertion in the catheter to open the valve and carry fluid into or out of the body.

8. A catheter as claimed in claim 7 when appendant to claim 5 or claim 6, in which the fluid flow member comprises a length of tubing with a nozzle at one end, the nozzle being shaped for insertion into the catheter tube through the valve to open the valve and carry fluid into or out of the body through the tubing.

9. A catheter as claimed in any one of the preceding claims in which the catheter tube is provided with shaped portions at each end to retain the tube in position in the body.

10. A catheter as claimed in claim 9, in which the catheter tube is provided at each end with portions which extend transversely from the tube to engage, respectively, an internal and an external surface of the body and retain the tube in position.

11. A catheter as claimed in claim 9 or claim 10, in which the length of the catheter tube between the shaped portions can be altered.

12. A catheter as claimed in any one of claims 9 to 11, in which the shaped portion

at one end, at least, of the catheter tube is formed separately from the tube and the length of the tube is selected before the separately-formed shaped portion is secured thereto.

13. A catheter as claimed in claim 12, in which the separately-formed shaped portion is at the external end of the tube and includes the valve.

14. A catheter as claimed in claim 12, in which the separately-formed shaped portion is at the internal end of the tube and includes an end closure for the tube and openings for connecting the bore of the tube with the interior of the body.

15. A catheter as claimed in claim 9 in which the shaped portions at the external end of the tube are formed integrally with the tube and the valve is formed separately from the tube and secured to the external end thereof.

16. A catheter as claimed in claim 10, in which the transversely-extending portions for engagement with the internal body surface are movable out of the transversely-extending position to permit insertion of the catheter in the body.

17. A catheter as claimed in claim 10, in which the transversely-extending portions for engagement with the internal body surface are deformable to permit insertion of the catheter in the body.

18. A catheter as claimed in any one of the preceding claims, the catheter being deformable over a rigid former to permit insertion of the catheter in the body.

19. A catheter as claimed in claim 18, in which the internal end of the catheter tube is at least partly closed over for engagement by the former.

20. A catheter as claimed in any one of the preceding claims, including a removable closure for the external end of the catheter tube.

21. A catheter as claimed in any one of the preceding claims, for use as a gastrostomy tube, the catheter being shaped for insertion in the stomach through a stoma in the abdomen.

22. A catheter as claimed in claim 21 when appendant to claim 8, in which the end of the tubing remote from the nozzle is connected to a source of fluid feed.

23. A catheter substantially as described herein with reference to, and as shown in, Fig. 2 or Figs. 6 to 8 or Figs. 9 and 10 or Fig. 11 or Fig. 12 or Fig. 13 of the accompanying drawings.

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